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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SIEW, JEFFREY

ART UNIT	PAPER NUMBER
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1637

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DATE MAILED: 08/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/046,786

Applicant(s)

DATTAGUPTA ET AL.

Examiner

Jeffrey Siew

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. **The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. ____" should follow the filing date of the parent application.** If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or

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120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,379,930. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-22 of the instant application are drawn to the composition, method of using or making thereof comprising reagents to perform nucleic acid amplification and inhibitory concentration of reversible inhibitor of an undesirable reaction..

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The sheer breadth of the claims encompass any inhibitor to any undesirable reaction. The specification supports the use of certain compounds in nucleic acid assay such as benzyl sulfide useful for releasing nucleic acids (see example 2). However, the specification does not provide sufficient support for any possible compound that inhibits any type of undesirable reaction in a nucleic acid amplification.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3,14-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 3,14-19 are indefinite because they are drawn to a method but no clear and defined steps are recited. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion and clearly refer back to the preamble of the claim. See *ex parte Erlich*, 3 USPQ2, p. 1011 (Bd. Pat. A.P. In. 1986). It is suggested that all claims be amended to set forth active steps.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Bloch et al (US5,565,339 Oct. 15, 1996).

Bloch et al teach the use of oil, grease or wax to inhibit PCR reagents from reacting too early to produce nonspecific products in a nucleic acid amplification (see whole doc. esp. col. 6 line 50-53). The method and composition is particularly suitable for storage of PCR reagents. They teach a containers to hold PCR reagents (see claims 1-7). In example 3 & 4 they describe combining test human genomic DNA to composition. They teach primers (see col. 22 line 18).

Applicant is reminded that the composition claims are read on their component parts and not on the intended use.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1-5 & 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Park et al (US6,153,412 Nov. 28, 2000).

Park et al teach a method of adding a stabilizing and sedimenting agent to PCR aqueous reaction mixture and lyophilizing. The PCR lyophilized reagent kit contains reaction buffer,

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dNTPS, DNA polymerase (see whole doc. esp. abstract, col. 3 lines 30-42). Stabilizers may include glycerol, glucose, polyol (see col. 3 lines 55-57). The addition of water soluble dye, bromophenol blue acts as a stabilizer for the reagents (see col. 3 lines 59-65). The reagent is then added to water to perform PCR.

The stabilizing reagent is in sufficient concentration to provide for stabilization but would be diluted in the subsequent use in the PCR amplification.

7. Claims 1-6,12 are rejected under 35 U.S.C. 102(e) as being anticipated by Coull et al (US6,110,676 Aug. 29, 2000).

Coull et al teach the use of PNA probes to block the amplification of undesired target during PCR reactions (see whole document esp. col. 21 line 19-col. 22 line 60).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (US6,153,412 Nov. 28, 2000) in view of Shen et al (US5,614,387 March 25, 1997).

The teachings of Park et al are described previously.

Park et al do not teach addition of primers.

Shen et al teach addition of primers in composition (see claim 1).

One of ordinary skill in the art at the time of the invention would have been motivated to combine the primers of Shen et al into Park et al's kit in order to quickly amplify and detect target sequence. It would have been prima facie obvious to further add primers for amplification Park et al's kit in order to eliminate the primer adding step in the amplification.

9. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (US6,153,412 Nov. 28, 2000) in view of Tessman et al (US5,532,145 July 2, 1996).

The teachings of Park et al are described previously.

Park et al do not teach addition of AMT.

Tessman et al teach the use of AMT to render contaminating amplifiable nucleic acid nonamplifiable in a mixture (see whole doc. esp. col. 4 line 19).

One of ordinary skill in the art at the time of the invention would have been motivated to further treat Park et al's composition by adding AMT as taught by Tessman et al in order to

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eliminate contaminating nucleic acids. Tessman et al state that many polymerases possess contaminating nucleic acids (see col. 21 lines 15-19). It would have been prima facie obvious to further treat Park et al's composition by adding Tessman et al's AMT and light treating the composition in order to eliminate the contaminating nucleic acids.

10. Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloch et al (US5,565,339 Oct. 15, 1996).

Bloch et al teach the use of oil, grease or wax to inhibit PCR reagents from reacting too early to produce nonspecific products in a nucleic acid amplification (see whole doc. esp. col. 6 line 50-53). The method and composition is particularly suitable for storage of PCR reagents. They teach a containers to hold PCR reagents (see claims 1-7). They teach a kit (see claim12).

Bloch et al do not teach a kit with the grease or wax per se .

One of ordinary skill in the art would have been motivated to incorporate the containers of PCR reagent and grease or wax in order to allow the practitioner to quickly access the reagents to perform the amplification. It was well known and commonly practiced in the art to design kits. It would have been prima facie obvious to incorporate Bloch et al's reagents into a kit for distribution to practitioners which would allow them to readily perform multiple amplifications.

11. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coull (US6,110,676 Aug. 29, 2000)

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Coull et al teach the use of PNA probes to block the amplification of undesired target during PCR reactions (see whole document esp. col. 21 lien 19-col. 22 line 60).

Coull et al do not teach a kit per se.

One of ordinary skill in the art would have been motivated to incorporate the containers of Coull et al's PNA probes, PCR reagents and primers in order to allow the practitioner to quickly access the reagents to perform the amplification. It was well known and commonly practiced in the art to design kits. It would have been prima facie obvious to incorporate Coull et al's reagents into a kit for distribution to practitioners which would allow them to readily perform multiple amplifications.

SUMMARY

12. No claims allowed.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m.

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If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.


JEFFREY SIEW
PRIMARY EXAMINER

July 27, 2003